# Module 8: Data for Abridged Applications and Specialised Products

**Date: 8 – 10 November 2023**

**LOCATION:** TOPRA OFFICE, LONDON, UK
**Module Leader(s):** Alenka Dražumerič and Eva Kopecna

## Day 1: Wednesday 8th November 2023

| Time (GMT) | Activity | Speaker |
|---|---|---|
| 08.45–9.00 | **Registration**<br>Welcome & introduction to the module learning objectives | Module Leaders |
| 09.00-10.00 | Lecture 1: **Revision of Regulatory Strategic Issues for Abridged Applications - A Regulatory Agency's Experience**<br>Legal basis<br>Definition of generics<br>Intellectual property<br>Regulatory procedures<br>Paediatric regulation<br>Submission strategy | Elspeth Gray, MHRA |
| 10.00–11.00 | Lecture 2: **CMC Drug Substance – Established Molecules**<br>CEPs, DMFs<br>Physicochemical properties<br>Setting drug substance specification<br>Manufacturing issues for drug substance<br>Containers<br>Stability requirements<br>TSE<br>Specific data requirements for other regions, i.e. LATAMA/APAC | Mojca Ule, Sandoz |
| 11.00–11.30 | **Morning break** | |
| 11.30–12.30 | Lecture 3: **CMC Data Requirements: Drug Product**<br>Line extension with different dosage forms<br>Generics product development and manufacture<br>Specifics of modified release, topical products, injections<br>Setting drug product specification<br>Stability requirements<br>Common deficiencies<br>Inspections<br>Specific data requirements for other regions, i.e. LATAM/APAC | Alenka Dražumerič, Medis |
| 12.30–13.30 | **Lunch** | |

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| 13.30–14.30 | Lecture 4: **Bioequivalence**<br>Pharmaceutical equivalence<br>Therapeutic equivalence<br>Design of bioequivalence studies<br>Biowaiver<br>Choice of reference and test products<br>Review of the revised guideline on bioequivalence | Dejan Krajcar, Sandoz |
| 14.30–15.30 | Lecture 5: **Non-clinical Considerations: Abridged Applications and Testing Strategies**<br>Bridging Tox<br>Combination products<br>Paediatric indications<br>Novel excipients<br>Environmental Risk Assessment | Michelle McDonald-Alexis, Parexel |
| 15.30–16.30 | Lecture 6: **Clinical considerations**<br>New Indications<br>New Routes of Administration<br>Additional dosage forms<br>New target population<br>Paediatric indications | Rozeta Mileva-Peceva, ALKALOID AD Skopje |

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## Date: Thursday 9th November 2023

| Time | Activity | Speaker |
|---|---|---|
| 08.45 | **Registration** | |
| 09.00–10.00 | Lecture 7: **Abridged Options US**<br>Abbreviated NDAs<br>Supplementary NDAs<br>505(b)(2) applications<br>Influence of ICH in the US<br>Role of the FDA and recent developments (i.e. fees, ObD) | Sarah Roberts, PRA Health Sciences |
| 10.00–11.00 | Lecture 8: **Drug Device Combinations**<br>Definition (Medicinal Product/Medical Device)<br>Medical Device legislation<br>Regulatory approval process<br>Drug/Device products (borderline products, medicated devices, drug delivery systems, drug device combinations) | Janine Jamieson, IPQ |
| 11.00–11.15 | **Morning break** | |
| 11.15–13.00 | **Case study 1** | Module Leaders |

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| 13.00–14.00 | **Lunch** | |
| 14.00–15.00 | Lecture 9: **Blood Products**<br>What are blood products?<br>Master files<br>Albumin as an excipient | Benedicte Deloux, Bio Products Lab |
| 15.00–16.00 | Lecture 10: **Inhalation Products**<br>Product types (nebulisers, MDIs, DPIs)<br>Quality/Safety/Efficacy<br>Product information (SmPC, labelling) | Mike Bateman, Diurnal Ltd. |

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### Date: Friday 10th November 2023

| Time | Activity | Speaker |
|---|---|---|
| 08.45 | **Registration** | |
| 09.00-10.00 | Lecture 11: **Radiopharmaceuticals**<br>What are Radiopharmaceuticals?<br>Examples of Radiopharmaceuticals use<br>Radiopharmaceuticals legislation<br>Manufacturing challenges<br>Specifics of Quality/Non-clinical/Clinical data Product information (SmPC, labelling) | Peter Bradley, GE Healthcare |
| 10.00–11.00 | Lecture 12: **Herbals**<br>Overview of legislation for herbals<br>Registration routes:<br>Well established use, traditional use<br>Specific requirements for herbals: Quality, Safety, Efficacy | Reinhard Länger, AGES |
| 11.00–11.15 | **Morning break** | |
| 11.15–13.00 | **Case study 2** | Module Leaders |
| 13.00–14.00 | **Lunch** | |
| 14.00–15.00 | Lecture 13: **Cosmetics**<br>EU Requirements of the Cosmetic Regulation<br>Ingredients & manufacture requirements<br>Responsible Person & Product Information File<br>Cosmetic Notification<br>Labelling & Cosmetovigilance<br>Cosmetic vs. Medicine – borderline issues | Tamsin Worrad-Andrews, Unilever |
| 15.00–15.15 | Summary and **Closure** of Module | Module Leaders |